IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re the Application of : **CHARI**

Application No. **09/671,995** Group Art Unit: **1624**

Filed: **September 29, 2000** Examiner: **M. Tran**

For: **Compositions and Methods for Treating Cancer Using immunoconjugates and Chemotherapeutic Agents**

Attorney Docket No: **104322.198US1**

Assistant Commissioner of Patents
Washington, DC 20231

Provisional Response to Restriction Requirement and Request for Reconsideration of Restriction Requirement under 37 CFR § 1.143

This Response is submitted in reply to the restriction requirement dated May 30, 2001, for which a response is due on or before June 30, 2001.

Applicant respectfully requests reconsideration of the restriction requirement dated May 30, 2001, for the reasons herein.

I. The First Restriction Requirement of March 15, 2001

On March 15, 2001, the Examiner issued the following restriction requirement:

Group I	Claims 1-32	Drawn to methods of treating cancer.
Group II	Claims 33-39	Drawn to methods of inhibiting cell growth.
Group III	Claims 40-41	Drawn to compositions and kits.
Group IV	Claims 42-43	Drawn to methods for treating autoimmune diseases.

The claims in Group I, claims 1-32, included methods for treating cancer by administering a chemotherapeutic agent and an immunoconjugate comprising a cell binding agent and an anti-mitotic agent (claim 1). The cell binding agent in claim 1 could be an antibody (claims 10-15). The anti-mitotic agent in claim 1 could be a maytansinoid (claims 6-7); a *Vinca* alkaloid (claims 8-9); a dolastatin (claims 8-9) or a cryptophycin (claims 8-9). The chemotherapeutic agent in claim 1 could be a taxane (claims 16-20), a platinum compound (claims 21-24), a camptothecin compound (claims 25-26), an inhibitor of DNA topoisomerase I compound (claim 27).

The Examiner did not restrict claim 1 to the particular chemotherapeutic agents, cell binding agents, and anti-mitotic agents presented in claims 1-32.

In response to the restriction requirement, Applicant elected Group III and added composition and kit claims that corresponded to pending method claims 2-32, ***which were not further restricted by the Examiner*** in the First Restriction Requirement dated March 15, 2001.

II. The Second Restriction Requirement of May 30, 2001

The Examiner now asserts that added claims 44-89 must be further restricted as follows:

Group I, Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a taxane.

Group II, Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a platinum compound.

Group III, Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of a camptothecin compound.

Group IV, Claims drawn to an anti-mitotic agent of maytansinoid, an antibody, and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I compound.

Group V, Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a taxane.

Group VI, Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a platinum compound.

Group VII, Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of a camptothecin compound.

Group VIII, Claims drawn to an anti-mitotic agent of *Vinca*, an antibody, and one chemotherapeutic agent of an inhibitor of DNA topoisomerase I compound.

III. The Second Restriction Requirement Is Not Proper

The Second Restriction Requirement and the Examiner's position asserting the necessity thereof is contrary to the Examiner's action in the First Restriction Requirement of March 15, 2001, in which ***the same claims, presented as method claims, were not restricted.*** In view thereof, Applicant respectfully submits that the Second Restriction Requirement is improper, and that claims 40-41 and 44-89 should be considered together, just like claims 1-32 were considered together in the First Restriction Requirement.

Moreover, the Second Restriction Requirement completely ignores claim 46 where the anti-mitotic agent is a dolastatin or a cryptophycin. Applicant respectfully submits that such a restriction requirement is improper. In support thereof, Applicant refers to the August 22, 2000, minutes from the Chemical Pharmaceutical Customer Partnership Meeting, which states:

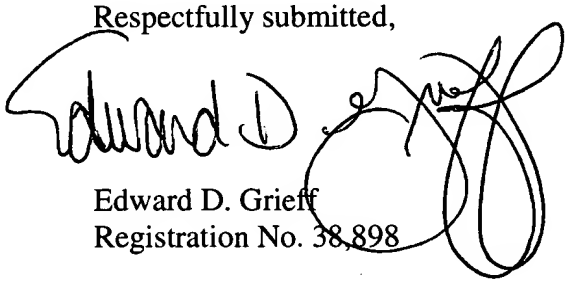
> Richard Schwartz presented on restriction practice. He stated that to make restriction practice work is very simple. First you divide by one proper election species or two by group. ***Conditions on restricting a claim is to sum up the parts which must equal the whole. A written descriptive support must exist for each part.*** Richard Schwartz also provided information on the election of species in Markush-Type generic claims and claims containing no Markush groups.

Applicant respectfully submits that the Patent Office's procedure for restriction practice has ***not*** been followed in the Second Restriction Requirement, and is improper in view of the First Restriction Requirement.

IV. Response to Second Restriction Requirement

In response to the Second Restriction Requirement, Applicant elects Group I, with traverse. Applicant respectfully requests reconsideration of the restriction requirement and consideration of all of the pending claims

Respectfully submitted,



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Date: June 26, 2001

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